

### **REMARKS**

In the present amendment, claims 1, 4, 11, 12, and 14 have been amended. In addition, claims 15-20 have been added. It is believed that the amended and newly added claims are supported by the originally filed application, and that no new matter is added.

#### **Information Disclosure Statement**

The Office Action indicates at page 2 that all references cited in the IDSes have been considered. As the Examiner has noted, however, reference AK on page 3 of the IDS submitted December 11, 2003 contains two references rather than one. This was an administrative error on the part of the Applicants' Representative.

It is Applicants' understanding that both references listed as reference AK on page 3 of the IDS submitted December 11, 2003 were considered by the Examiner, specifically:

- Lyon et al., Nature, Vol. 227, pgs. 1217-1219 (1970) (cited in item AJ, and again in item AK)
- Gaspar et al., PNAS, Vol. 88, pgs. 8606-8610 (1991) (cited partially in item AK).

Enclosed herewith is a PTO-1449 form containing the complete citation for the Gaspar et al. reference that was partially listed as reference AK on page 3 of the IDS submitted December 11, 2003, as well as a copy of this reference. In the interest of clarifying the record, Applicants request that the Examiner indicate that this reference was considered by returning a copy of the initialed PTO-1449 form.

#### **35 U.S.C. § 101**

Claims 1-14 stand rejected as purportedly not being supported by either a credible, specific, and substantial utility or a well established utility. That rejection is respectfully traversed to the extent the rejection applies to the claims as amended.

Applicants note that claims 1, 11, and 14, as amended herein, require that the androgen receptor nucleic acid is expressed in the transgenic non-human mammal. It is submitted that the subject matter of amended claims 1, 11, and 14 (and claims depending therefrom) are supported by a specific and substantial asserted utility and/or a well established utility. Moreover, it is submitted that claim 8 (and claims depending therefrom) is supported by a specific and

substantial asserted utility and/or a well established utility, including use to make the claimed transgenic non-human mammals. Withdrawal of this rejection is requested.

**35 U.S.C. § 112, first paragraph**

Claims 1-14 stand rejected as purportedly failing to comply with the enablement requirement. That rejection is respectfully traversed to the extent the rejection applies to the claims as amended, which now specify that the transgenic non-human mammal expresses the androgen receptor nucleic acid.

Applicants submit that no undue experimentation is required to practice the claimed invention. The examples in the specification provide for the generation and breeding of transgenic mice harboring the ARE-LUC/CMV-rAR construct, wherein the expression of the transgene was detected. Moreover, the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. It is submitted that the amended claims comply with the enablement requirement. Withdrawal of this rejection is requested.

**35 U.S.C. § 112, second paragraph**

Claims 4-7, 11, and 12 stand rejected as purportedly being indefinite. It is respectfully submitted that these claims, as amended herein, are not indefinite. Withdrawal of this rejection is respectfully requested.

**CONCLUSION**

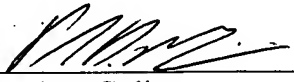
In view of the foregoing amendments and remarks, allowance of the application is respectfully requested. The Examiner is invited to contact the undersigned if there are any questions concerning the prosecution of this application.

Appl. No. 10/620,514  
Docket No. D0287 NP

The Commissioner is authorized to charge Deposit Account 19-3880 (Bristol-Myers Squibb Company) for any requisite fees due or to credit any overpayment.

Respectfully submitted,

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